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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2006-0188]

RIN 0579-AC37

Genetically Engineered Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for information.

SUMMARY: The Animal and Plant Health Inspection Service (APHIS) is seeking public comment and scientific and technical empirical data and information concerning ongoing and future research on genetically engineered animals. APHIS' interest is to ensure that genetically engineered animals imported into the United States or moved interstate do not present risks to U.S. livestock health. We also seek comment on what types of actions and approaches APHIS should consider in addressing any such risks that would complement the Food and Drug Administration's (FDA's) oversight, described in draft guidance elsewhere in this issue of the Federal Register.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS

-2006-0188 to submit or view comments and to view supporting and related materials available electronically.

- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS-2006-0188, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2006-0188.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

FOR FURTHER INFORMATION CONTACT: Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; 301-734-5720.

SUPPLEMENTARY INFORMATION:

Background

In 1986, the Office of Science and Technology Policy (OSTP) under the Executive Office of the President published a policy document known as the Coordinated Framework for the Regulation of Biotechnology (the Coordinated Framework).[1] This policy document describes the system for coordinating the activities of the Federal agencies responsible for regulating all

[1] Coordinated Framework for the Regulation of Biotechnology: June 26, 1986; 51 FR 23302; http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf

GE organisms[2]: The Environmental Protection Agency (EPA), the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA), specifically the Animal and Plant Health Inspection Service (APHIS). The foundation of the Coordinated Framework is that existing health and safety laws administered by these Federal agencies provide a sound network of agency authorities for the regulation of GE organisms and products.

Roles of APHIS and Other Agencies in the Regulation of GE Animals

USDA and FDA both have authorities relevant to the oversight of GE animals. FDA has authority over new animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 321 et seq.). Elsewhere in the issue of the Federal Register, FDA is announcing the availability of draft guidance for public comment clarifying its oversight of GE animals under the new animal drug provisions of the FFDCA. The draft guidance explains that where a recombinant DNA construct in a GE animal is intended to affect the structure or function of the body of the GE animal, that construct is a new animal drug[3] regardless of the intended use of products that may be produced by the GE animal. The FFDCA requires that each new animal drug be approved through a new animal drug application (NADA) based on a demonstration that it is safe and effective for its intended use. FDA has been working with developers of GE animals for almost 20 years and the draft guidance is intended to clarify requirements and recommendations for producers and developers of GE animals and their products.

[2] In addition to discussing the regulatory responsibilities of these agencies for GE organisms and other products, the Coordinated Framework also discusses the responsibilities of agencies with jurisdiction over GE research (the National Institutes of Health, the National Science Foundation, EPA, and USDA's Agricultural Research Service).
[3] In accordance with the definition of "new animal drug" in 21 U.S.C. 321(v).

The USDA has provided Federal leadership in protecting U.S. livestock health for more than 120 years. APHIS is authorized, under the Animal Health Protection Act (AHPA) (7 U.S.C. 8301 et seq.), to protect the health of U.S. livestock by preventing the introduction and spread of livestock diseases and pests into and within the United States. Based on that authority, APHIS may broadly consider the potential effects of animals with GE traits on the health of the overall U.S. livestock population, while FDA is more focused on the direct effects of genetic engineering on individual animals based on their authority under the FFDCA. Given these complementary authorities, APHIS and FDA have been discussing their respective roles in overseeing GE animals for some time. FDA's release for public comment of its draft guidance on GE animals provides an excellent opportunity for APHIS to solicit public comment on the potential effects of animals with GE traits on U.S. livestock health.

APHIS particularly seeks the following information:

1. What research on GE animals is currently being conducted or planned for the future?

2. What, if any, implications would activities such as the importation and interstate movement of such animals have for the health of the U.S. livestock population?

3. What, if any, activities should APHIS consider with respect to U.S. livestock health under the AHPA that would complement the requirements and recommendations described in FDA’s draft guidance?

APHIS welcomes comments and scientific and technical information and data relevant to these issues. We will consider all comments and information we receive in determining the appropriate role for APHIS with regard to GE animals and will continue to collaborate closely with FDA.

This action has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.

Done in Washington, DC, this 16th day of September 2008.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

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